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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,801	05/30/2001	John W. Cherwonogrodzky	3929-3	5677

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EXAMINER	
FORD, VANESSA L	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/866,801	CHERWONOGRODZKY, JOHN W.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *63-91* is/are pending in the application.

4a) Of the above claim(s) *83-91* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *63-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

1. This Office action is responsive to Applicants amendment and response filed May 18, 2004. Claims 1-62 have been cancelled. Claims 63-91 have been added. Claims 83-91 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Rejection Withdrawn

3. In view of Applicant's amendment and Response, the following rejections are withdrawn:

a) rejection of claims 30-35, 37-39, 41 and 45-46 under 35 U.S.C. 102(b), pages 6-8 of the previous Office action.

b) rejection of claims 30-36, 41-42, 44-51, 55-56, 58 and 62 under 35 U.S.C. 102(b), pages 8-9 of the previous Office action.

c) rejection of claim 43 under 35 U.S.C. 102(b), pages 10-12 of the previous Office action.

d) rejection of claim 54 under 35 U.S.C. 112, second paragraph, page 12 of the previous Office action.

e) rejection of claim 54 under 35 U.S.C. 102(b), pages 13-14 of the previous Office action.

f) rejection of claims 52 and 53 under 35 U.S.C. 102(b), pages 14-15 of the previous Office action.

Rejections Maintained

4. The rejection under 35 U.S.C. 102(b) as anticipated by Pasarell et al is maintained for newly submitted claims 63-65, 67-73, 75-76 and 78-79 the reasons set forth on pages 3-4, paragraph 5 of the previous Office Action.

The rejection was on the grounds that that Pasarell et al teach concentrated culture filtrate antigens that were obtained from the genera *Alternaria, Bipolaris, Curvularia, Dactylaria, Drechslera, Embellisia, Exserohilum, Fusarium, Helminthosporium, Microsporum, Scolecobasidium and Scopulariopsis.* Pasarell et al teach that the culture antigens were incubated and aerated on a rotating shaker (p. 1655, 2nd column). Pasarell et al teach that the concentrated culture filtrate antigens was used to immunize two New Zealand White female rabbits. Pasarell et al teach that an emulsion of 1 ml of each control antigen and 1 ml of Freund incomplete adjuvant was injected intramuscularly into the New Zealand rabbits. *Alternaria, Dactylaria, Drechslera, Embellisia, Fusarium, Micosporum, Scolecobasisum and Scolecobasidium and Scopulariopsis* did not have common antigens when tested against the antisera. Antigens of *Helminthosporium* only reacted with its own sera and there were no cross-reactions with any other antigens tested (p. 1656, 1st column). Pasarell et al teach that antisera prepared from *E. rostratum* recognized antigens prepared from *E. holmii.* Pasarell et al teach that a similar result was observed with antisera prepare from *E. mcginnisii* and *E. longirostratum.* Pasarell et al that common antigens are shared between the genera of *Bipolaris* and *Curvularia* (p. 1656). The process limitation of the supernatant being prepared and used at 20°C is a matter of design choice. Although the reference appears to disclose the same cell culture supernatant claimed by the Applicants, the reference does not disclose the cell culture supernatant being prepared at the same temperature as the claimed process. However, the production of a cell culture supernatant by a particular process does not impart novelty or unobviousness to a cell culture supernatant when the same cell culture supernatant is taught in the prior art. This particularly true when properties of the cell culture supernatant are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964

(CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). The fungal or yeast culture of Pasarell, et al appears to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's fungal or yeast culture supernatant with the fungal or yeast culture supernatant of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i.e., that the fungal or yeast culture supernatant of the prior art does not possess the same material structural and functional characteristics of the claimed fungal or yeast culture supernatant). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that Pasarell used an Amicon PM10 filter which discard anything in the filtrate that is less than 10,000 m.w. while retaining large proteins. Applicant urges that the presently claimed invention provides a fungal cell culture supernatant containing fungal or yeast components shedded to the supernatant during culturing. Applicant urges that the presently claimed invention defines a supernatant which retained all or substantially all of the components in the supernatant such as for example aflatoxins which have a molecular weight of for example less than 400 m.w. Applicant urges that the reference teaches away from the claimed invention. Applicant urges that the cited reference fails to teach each and every aspect of the presently claimed invention.

Applicant's arguments filed May 18, 2004 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant is arguing limitations that are not in the claims. Pasarell et al teach concentrated culture filtrate antigens that were obtained from the genera *Alternaria, Bipolaris, Curvularia, Dactylaria, Drechslera, Embellisia, Exserohilum, Fusarium, Helminthosporium, Microsporum, Scolecobasidium*

and Scopulariopsis. Pasarell et al teach that the culture antigens were incubated and aerated on a rotating shaker (p. 1655, 2nd column). There is no requirement in the claims that requires that the cell culture supernatant be filtered with a specific filter or a specific filtration step. Although the reference appears to disclose the same cell culture supernatant claimed by the Applicants, the reference does not disclose the cell culture supernatant being prepared at the same temperature as the claimed process. However, the production of a cell culture supernatant by a particular process does not impart novelty or unobviousness to a cell culture supernatant when the same cell culture supernatant is taught in the prior art. This particularly true when properties of the cell culture supernatant are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). It should be noted that the claims are drawn to a product (a cell culture supernatant) which would inherently possess all of the same characteristics as the claimed cell culture supernatant. Applicant has provided no side-by-side comparison to show that the fungal cell culture supernatant of the prior art differs from the claimed fungal cell culture supernatant. Therefore, the teachings of Pasarell et al anticipate the claimed invention.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 63-67 and 72 are rejected under 35 U.S.C. 102(b) as anticipated by Cotty *(U.S. Patent No. 5,171, 686, published December 15, 1992).*

Claims 63-67 and 72 are drawn an antigenic composition for detecting antibodies from a sample of a test subject, said composition comprising a fungal or yeast cell culture supernatant containing fungal or yeast components shed into the supernatant during culturing; said antigenic composition being characterized by a reduction of antigenic activity of less than 20%, as measured by ELISA, after treatment with protease in 0.25M TRIS buffer at PH 7.2.

Cotty teaches compositions comprising *Aspergillus flavus* which produce fungal aflatoxin (columns 2-3). Cotty teaches that the isolates produced aflatoxins in culture and during infection (column 2 and 5). Although the reference appears to disclose the same cell culture supernatant claimed by the Applicants, the reference does not disclose the cell culture supernatant being prepared at the same temperature as the claimed process. However, the production of a cell culture supernatant by a particular

process does not impart novelty or unobviousness to a cell culture supernatant when the same cell culture supernatant is taught in the prior art. This particularly true when properties of the cell culture supernatant are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Claim limitations such as "wherein said supernatant comprises a mixture of antigens which are capable of binding to a different fungal or yeast species", "wherein said components are capable of binding said antibodies" and "wherein said supernatant displays specific antibody affinity such that only antibodies of a specific fungus or yeast bind to said components" would be inherent in the teachings of the prior art. The claim limitation "composition for detecting levels of antibodies from a sample of a test subject" is being viewed as a limitation of intended use.

Since the Office does not have the facilities for examining and comparing applicant's antigenic composition with the antigenic composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i.e., that the antigenic composition of the prior art does not possess the same material structural and functional characteristics of the claimed antigenic composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

6. Claims 63-68, 72, 74, 76 and 78-79 are rejected under 35 U.S.C. 102(b) as anticipated by Groopman et al *(U.S. Patent No. 4,859, 611, published August 22, 1989).*

Claims 63-68, 72, 74, 76 and 78-79 are drawn an antigenic composition for detecting antibodies from a sample of a test subject, said composition comprising a fungal or yeast cell culture supernatant containing fungal or yeast components shed into the supernatant during culturing; said antigenic composition being characterized by a reduction of antigenic activity of less than 20%, as measured by ELISA, after treatment with protease in 0.25M TRIS buffer at PH 7.2.

Groopman et al teach *Aspergillus* supernatant cultures which produce fungal aflatoxin (column 4) Groopman et al teach anti-aflatoxin antibodies (columns 5-6). Groopman et al et al teach vaccine compositions aflatoxins formulated in Freund's complete adjuvant which were used to immunize mice (columns 4-5) . The prior art teaches the claim limitation "wherein said supernatant displays specific antibody affinity such that only antibodies of a specific fungus or yeast bind to said components" since the prior art teaches that anti-aflatoxin are specific to *Aspergillus* (columns 5-6). The prior art also teaches the claim limitation "...composition for detecting levels of antibodies from a sample of a test subject" because the prior art teaches detecting and isolating aflatoxins in fluid samples (column 8). Although the reference appears to disclose the same cell culture supernatant claimed by the Applicants, the reference does not disclose the cell culture supernatant being prepared at the same temperature as the claimed process. However, the production of a cell culture supernatant by a

particular process does not impart novelty or unobviousness to a cell culture supernatant when the same cell culture supernatant is taught in the prior art. This particularly true when properties of the cell culture supernatant are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Claims limitations such as "wherein said supernatant comprises a mixture of antigens which are capable of binding to different fungal or yeast species" and "wherein said components are capable of binding said antibodies" would be inherent in the teachings of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's antigenic composition with the antigenic composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i.e., that the antigenic composition of the prior art does not possess the same material structural and functional characteristics of the claimed antigenic composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

7. Claims 63-65, 67-68, 73 and 78-81 are rejected under 35 U.S.C. 102(b) as anticipated by Dubeau et al *(Biotechnology Letters, 1987, Vo. 9, No. 4, p. 275-280).*

Claims 63-65, 67-68, 73 and 78-81 are drawn an antigenic composition for detecting antibodies from a sample of a test subject, said composition comprising a fungal or yeast cell culture supernatant containing fungal or yeast components shed into

the supernatant during culturing; said antigenic composition being characterized by a reduction of antigenic activity of less than 20%, as measured by ELISA, after treatment with protease in 0.25M TRIS buffer at PH 7.2.

Dubeau et al teach a *Chaetomium cellulolyticum* culture supernatant (see the Abstract). Although the reference appears to disclose the same cell culture supernatant claimed by the Applicants, the reference does not disclose the cell culture supernatant being prepared at the same temperature as the claimed process. However, the production of a cell culture supernatant by a particular process does not impart novelty or unobviousness to a cell culture supernatant when the same cell culture supernatant is taught in the prior art. This particularly true when properties of the cell culture supernatant are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Claims limitations such as "wherein said supernatant comprises a mixture of antigens which are capable of binding to different fungal or yeast species", wherein supernatant comprises aflatoxin", "wherein said components are capable of binding said antibodies" and "wherein said supernatant displays specific antibody affinity such that only antibodies of a specific fungus or yeast bind to said components " would be inherent in the teachings of the prior art. The claim limitation "composition for detecting levels of antibodies from a sample of a test subject" and "vaccine" are being viewed as a limitation of intended use.

Since the Office does not have the facilities for examining and comparing applicant's antigenic composition with the antigenic composition of the prior art, the

burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i.e., that the antigenic composition of the prior art does not possess the same material structural and functional characteristics of the claimed antigenic composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

8. Claims 63-64, 67, 68, 70-72, 77-78 and 82 are rejected under 35 U.S.C. 102(b) as anticipated by Honbo et al *(Sabouraudia: Journal of Medical and Veterinary Mycology, 1984, 22, 301-310).*

Claims 63-64, 67, 68, 70-72, 77-78 and 82 are drawn an antigenic composition for detecting antibodies from a sample of a test subject, said composition comprising a fungal or yeast cell culture supernatant containing fungal or yeast components shed into the supernatant during culturing; said antigenic composition being characterized by a reduction of antigenic activity of less than 20%, as measured by ELISA, after treatment with protease in 0.25M TRIS buffer at PH 7.2.

Honbo et al teach *Cladosporium* culture supernatants (page 302). Honbo et al teach that the *Cladosporium* culture supernatants were formulated in Freund's. incomplete adjuvant and used to immunize rabbits (page 3030). Although the reference appears to disclose the same cell culture supernatant claimed by the Applicants, the reference does not disclose the cell culture supernatant being prepared at the same temperature as the claimed process. However, the production of a cell culture supernatant by a particular process does not impart novelty or unobviousness to a cell

culture supernatant when the same cell culture supernatant is taught in the prior art. This particularly true when properties of the cell culture supernatant are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). The claim limitation "composition for detecting levels of antibodies from a sample of a test subject" is being viewed as a limitation of intended use.

Since the Office does not have the facilities for examining and comparing applicant's antigenic composition with the antigenic composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i.e., that the antigenic composition of the prior art does not possess the same material structural and functional characteristics of the claimed antigenic composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

10. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
March 19, 2005

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